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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,490	02/07/2002	J. Alexander Marchosky	JMA 2977.1	2740

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,490	MARCHOSKY, J. ALEXANDER	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,18,32,50,54-60 and 65-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,18,32,50,54-60 and 65-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/28/03 &07/08/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment A and B filed 07/07/2002 and 03/17/03; IDS filed 07/08/02 and 06/13/03. Claims 5-17, 19-31, 33-49, 51-53 and 61-64 are cancelled. New claims 65-76 are added. Claims 1-4, 18, 32, 50, 54-60 and new claims 65-76 are pending.

Priority

1. This application claims to be a division of Application No. 09/606, 768, filed 29th June 2000. The disclosure of the divisional application should be the same as the disclosure of the earlier filed application. However, page 2, paragraph 1, starting with "various ..." and ending on page 3 with "unknown" was amended in the parent application. Also, page 16, second paragraph starting with "the scaffolding ..." and ending at page 17 with "20-40%" was amended in the parent application. That amendment is not done in the present divisional application. The examined divisional disclosure cannot be different from the parent disclosure.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 18, 56, 68 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Muschler (US 6,049,026).

Muschler teaches a composition comprising hyaluronic acid, demineralized bone matrix and cancellous bone. In addition to the components of the composition listed above, the composition of Muschler may also contain fibroblast growth factors, platelet derived growth factors, fibronectin molecules, epithelial growth factors and bone morphogenic proteins. See column 2, lines 28-35 and column 4, lines 4-68. Muschler meets the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4, 18, 32 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrie et al. (US 6,017,940) and Brown et al. (5,629,287).

Petrie et al. teaches compositions that promote tissue growth and the composition comprises osteogenic materials and growth factors selected from the group consisting of epidermal growth factor, fibroblast growth factor, platelet-derived growth factor, transforming growth factor and bone morphogenetic proteins (column 6, lines 5-45).

Brown et al. teaches a composition comprising fibroblast growth factor, epidermal growth factors, endothelial derived growth factor and fibrinectin (column 2, lines 7-17). Brown et al. teaches a method for treating bone defect wherein the method comprises administering to a subject one or more agents selected from the group consisting of bone morphogenetic factors, anti-resorptive agents, osteogenic agents, cartilage derived morphogenic proteins, growth hormones and differentiating factors (claims 1, 7 and 8).

The compositions of Petrie et al. and Brown et al. are utilized to treat bone defect. One of ordinary skill in the art would know routine experimental procedures to prepare the individual compositions and a combination of both compositions to treat bone defect. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Petrie et al. and Brown et al. One having ordinary skill in the art would have been motivated to combine the compositions of Petrie et al. and Brown et al. into one composition because the parts of the individual compositions overlap and because both compositions are applicable to treating bone defect.

6. Claims 3, 32, 50, 57-60, 65-67 and 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (6,049,026) in view of applicants admitted prior art..

Muschler is discussed above. Regarding claims 65-67 and 70-74 on amounts of the various components of the composition, (in re Aller), amounts or concentration would not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating that the recited amounts of the various components provide unusual results. The composition of Muschler does not contain chitosan or derivatives thereof. However, instant claim 1 admits that chitosan and hyaluronic acid are equivalent and since they are equivalent, they can be interchanged. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the composition of Muschler. One having ordinary skill in the art would have been motivated to substitute chitosan or its derivative for hyaluronic acid according to applicants' admitted prior art of the equivalency of hyaluronic acid and chitosan, with the expectation of producing a composition that is effective for bone growth and strengthening.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 54 and 55 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 47 and 48 of prior U.S. Patent No. 6,372,257. This is a double patenting rejection.

10. Claims 1-4, 18, 32, 50, 56-60 and 65-76 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,372,257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claim encompasses the issues claims; the dependent claims recite amounts.

Claim Objections

11. Claim 57 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech Center 1600